

New PCT National Phase Application
Docket No. 32860-001019/US

SUBSTITUTE SPECIFICATION

Description

METHOD AND DEVICE FOR VISUALLY SUPPORTING ~~ASSISTING~~ AN ELECTROPHYSIOLOGY ~~ELECTROPHYSIOLOGICAL~~ USE OF A CATHETER APPLICATION ~~IN THE~~ HEART

[0001] This application is the national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/EP2004/009446 which has an International filing date of August 24, 2004, which designated the United States of America and which claims priority on German Patent Application number 103 40 546.1 filed September 1, 2003, the entire contents of which are hereby incorporated herein by reference.

Field

[0002] The present invention generally relates to a method and/or to a device for visually supporting an electrophysiology catheter application in the heart. For example, it may relate to one, whereby electroanatomical 3D mapping data of an area of the heart to be treated, which are provided during the performance of catheter application, are visualized.

Background

[0003] The treatment of cardiac arrhythmia has changed considerably since the introduction of the technology of catheter ablation by ~~means~~ way of high-frequency current. In this technology, an ablation catheter is introduced into one of the heart chambers via veins or arteries under X-ray control and the tissue causing the cardiac arrhythmia is removed by high-frequency current.

[0004] The prerequisite for performing a catheter ablation successfully is that the cause of the cardiac arrhythmia is

accurately located in the heart chamber. This locating is done via an electrophysiological investigation during which electrical potentials are detected spatially resolved with a mapping catheter introduced into the heart chamber. This electrophysiological investigation, the so-called electroanatomical mapping, thus provides 3D mapping data which can be displayed on a monitor. In many cases, the mapping function and the ablation function are combined in one catheter so that the mapping catheter is also an ablation catheter at the same time.

~~[0004]~~ A known electroanatomical 3D mapping method such as can be performed by ~~means-way~~ of the carto system by the company Biosense Webster Inc., USA, is based on electromagnetic principles. Underneath the examining table, three different low-intensity alternating magnetic fields are built up. Using integrated electromagnetic sensors at the catheter_

[0005] point of the mapping catheter, it is possible to measure the voltage changes induced by catheter movements within the magnetic field and to calculate the position of the mapping catheter at any time with the aid of mathematical algorithms. Probing the endocardial contour of a heart chamber point by point with the mapping catheter and simultaneously detecting the electrical signals produces an electroanatomical three-dimensional map in which the electrical signals are reproduced color coded.

[0006] As a rule, the orientation of the operator required for guiding the catheter has hitherto been effected via fluoroscopic visualization. Since, in electroanatomical mapping, the position of the mapping catheter is known at any time with this technology, the orientation can also take place by continuous representation of the catheter point in the electroanatomical map after a sufficiently large number of measuring points has been detected, so that fluoroscopic imaging technology with X-ray screening can be omitted at this stage.

[0007] A fundamental problem in performing the catheter ablation inside the heart is that it has hitherto not been possible to provide optimal orientation of the operator during the guidance of the catheter. A more accurate representation of the morphological environment during the guidance of the catheter which, on the one hand, increase the accuracy during the catheter ablation and, on the other hand, of shortening the time for performing the electroanatomical mapping. Furthermore, the X-ray screening still required for the electroanatomical mapping in many cases could be reduced or avoided in that the X-ray dose applied could also be reduced.

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~~[0008]~~ To improve the orientation of the operator when guiding the catheter, different techniques are known. In one technique, a special catheter with an_

[0008] ultrasonic probe is used as is offered, for example, by company Siemens AG Medical Solutions under the title Acunav. Parts of the target tissue to be removed, together with the catheter, can be visualized in real-time via a two-dimensional ultrasonic detection of the environment and of a part of the catheter. However, using such a catheter does not supply three-dimensional image information. The ultrasonic representation can only be used, therefore, in order to insert, for example, a so-called loop catheter into the opening of the pulmonary vein. After the loop catheter has been positioned, tissue removal around the opening of a pulmonary vein can be performed by visualizing both the loop catheter and the ablation catheter by ~~means~~ way of X-radiation.

[0009] In another known technique, a loop catheter is placed at the opening of the pulmonary vein without the support of imaging 2D ultrasonic technology by applying a contrast medium via a catheter placed in the left atrium in the area of the pulmonary vein opening under X-ray screening. During this process, the contrast medium becomes distributed and a small proportion leaves with the blood flow via the pulmonary vein. This short-time visualization of the pulmonary vein enables the loop catheter to be placed in the opening. The catheter ablation can then be performed as with the above-mentioned technique.

[0010] A technique is also known in which the opening of the pulmonary vein is located by electroanatomical mapping of the left atrium and of the pulmonary veins by first introducing the mapping catheter into the pulmonary vein and then pulling it back until electrical activity of the atrium is detected. This position corresponds to the position of the opening of the pulmonary vein around which the target tissue is to be removed.

SUMMARY

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[0011]

It is ~~the~~ an object of at least one embodiment of the present invention to specify a method and a device for visually supporting an electrophysiology catheter application in the heart which provides for, for example, improved orientation during the guidance of the catheter during the catheter application, particularly in electroanatomical mapping and/or during a catheter ablation.

~~[0013] The object is achieved by the method and the device according to patent claims 1 and 15. Advantageous embodiments of the method and of the device are subject matter of the subclaims or can be found in the subsequent description and the exemplary embodiments.~~

[0012] In the present method of at least one embodiment, for visually supporting an electrophysiology catheter application in the heart, particularly a catheter ablation, 3D image data of a body region containing the area to be treated are first recorded by ~~means~~ way of a tomographical 3D imaging method before the catheter application is carried out. The area to be treated, or at least significant portions of it, is then extracted from the 3D image data. The resultant selected 3D image data and the electroanatomical 3D mapping data provided are finally correlated in the correct position and dimension and, preferably while the catheter application is being performed, are visualized next to one another at the same time in the correct position and dimension.

~~[0015] At least one embodiment of t~~The present method and/or the associated device thus provide the operator with assistance for orientation within the heart by showing the anatomical 3D image data and the 3D mapping data next to one another with the same orientation and scaling on one or more display panels or monitors. This makes it possible to identify both the

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electrophysiological properties of the tissue and the
associated anatomical environment in real_~

[0013] time during the catheter application. In this context, the visualization can be provided both in the control room and in the workroom in the cardiac catheter laboratory.

[0014] For recording the 3D image data, methods of X-ray computer tomography, of magnetic resonance tomography or of 3D ultrasonic imaging can be used, for example. Combinations of these imaging methods are also possible, of course. It is only necessary to pay attention to the fact that the 3D image recordings take place in the same heart phase as the electro-anatomical 3D mapping data provided so that in each case the same state of the heart is observed. This can be ensured with the familiar technology of ECG gating during the recording of the image data and of the electroanatomical mapping data.

[0015] Correlating the electroanatomical 3D mapping data with the selected 3D image data in the correct dimension and position can be done by ~~means~~ way of different techniques. One possibility ~~consists~~ resides in registration between the respective data by visually matching a 3D surface profile extracted by segmentation with the representation of the electroanatomical 3D mapping data. Furthermore, artificial markers or natural distinct points can be used which can be recognized in both records. Apart from the area to be treated, a neighboring area can also be used for the registration if it is contained in the existing data.

[0016] In an advantageous embodiment of the method and/or of the device, the registration takes place in a first stage in which only a relatively small portion of the electroanatomical 3D mapping data is present, with the aid of artificial markers or of distinct points, and in one or more subsequent stages in which a greater number of electroanatomical 3D mapping data is already present, by surface matching. In this manner, the registration is improved with the increasing number of

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electroanatomical 3D mapping data during the catheter
application.

[0017] The selected 3D image data can be represented by ~~means~~ way of a volume rendering technique. In a further embodiment, an extracted 3D surface profile is represented by a polygonal grid as is known from the field of computer graphics. The representation can be performed with an adjustable volume-rendering transfer function.

[0018] ~~The~~ At least one embodiment the present device for performing at least one embodiment of the method comprises includes one or more input interfaces for the electroanatomical 3D mapping data and the 3D image data recorded by means of an imaging tomographic method. The device has an extraction module for extracting an area which is to be treated, or significant portions of it, from the 3D image data, said extraction module providing selected 3D image data. This extraction module is connected to a registration module which is designed for correlation of the electroanatomical 3D mapping data and the selected 3D image data in the correct position and dimension. This registration module, in turn, is connected to a visualization module which provides the 3D mapping data and the selected 3D image data for visualization such that they can be shown in the correct position and dimension next to one another using one or more display units.

[0019] The individual modules of the device are constructed in different embodiments corresponding to the performance of the different embodiments of the method described in the text which follows.

[0020] In the text which follows, an embodiment of the present method and associated device will again be explained in greater detail in connection with the figure. For this purpose, the figure shows the individual steps in the performance of an

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embodiment of the present method and individual modules of the
associated device, respectively.

[0021] In a first step 1 in an embodiment of the present method, the 3D image data of the body region which particularly contains the heart chamber to be treated are recorded. During the recording of these 3D image data, a larger part of the heart can also be included for a later registration. The 3D image data are recorded by ~~means~~ way of a method of tomographic 3D imaging such as, for example, X-ray computer tomography, magnetic resonance tomography or 3D ultrasonic techniques. During the recording of the 3D image data, care must be taken that these image data are in each case recorded for the same heart phase for which the electroanatomical 3D mapping data will also be provided later. This is ensured by ECG gating of the image recording and recording of the 3D mapping data, for example by referring to a percentage of the RR interval or to a fixed time interval before or after the R peak.

[0022] During the performance of an embodiment of the method, it is of importance to record high-resolution image data of the heart chamber which is electroanatomically measured during the catheter application. Preferably, a contrast medium in association with a test bolus or bolus tracking is therefore used for recording the 3D image data.

[0023] As a rule, electrophysiological procedures are performed in one of the heart chambers, so that 3D mapping data from the heart chamber to be treated are provided. In an embodiment of the present application, heart chambers are to be understood as both ventricles and atria. For visualization in line with an embodiment of the present method, the image data from this heart chamber, or at least significant portions of it, are extracted from the recorded 3D image data. For extraction step 2 it is possible to use the following techniques or else a combination of these techniques.

~~[0026]~~—In one refinement of an embodiment of the method, extraction 2 can be performed by ~~means—~~way of "volume clipping". This involves_—

[0024] interactively using an input interface 8 to make successive settings for a number of clip levels, which limit a 3D image available from the 3D image data to a subvolume which contains the heart chamber to be treated.

[0025] Another possible technique for extraction 2 involves "volume punching", in which successive punching operations are performed interactively in order to mask out irrelevant parts of the 3D image available from the 3D image data. This may also concern parts of the heart which are not relevant to the later representation.

[0026] Another technique involves segmenting the 3D image data in order to obtain a 3D surface profile of the heart chamber in question and optionally of vessels adjacent to it. This segmentation can be used for later representation of the surface profile of these objects and, in one advantageous refinement of an embodiment of the method, also for correlation with the 3D mapping data in the correct position and dimension.

[0027] The segmentation of the heart chamber to be treated - or other chambers or heart vessels - can take place in the form of a 2D segmentation in individual layers. One possibility ~~consists~~ resides in performing a fully automatic segmentation of all layers of the heart chamber obtained by an embodiment of the imaging method. As an alternative, one or more of the layers can also be segmented interactively by an operator and the layers following in each case can be segmented automatically on the basis of the prior knowledge of the layers already segmented. The interactive segmentation of individual layers can also be supported by semiautomatic techniques such as, for example the technique of active contours. After the segmentation of all individual layers, the 3D surface profile of the heart chamber can then be reconstructed.

[0028] The segmentation can also take place as 3D segmentation of the heart chamber to be treated - or of other chambers or heart vessels - by ~~means~~way of known 3D segmentation techniques. Examples of such 3D segmentation techniques are the threshold technique or the technique of region growing. If these fully automatic 3D segmentation algorithms do not work reliably in individual cases, an interactive input capability for an operator can be provided in order to be able to specify, for example, gray scale thresholds or spatial blockers.

[0029] Extraction 2 is performed in the extraction module 11 of the present device 10. This extraction module 11 receives the recorded 3D image data via an appropriate input interface 14. In the same way, the device 10 is supplied with the 3D mapping data via the same or another interface 15, usually continuously during the period of the electrophysiological catheter application.

[0030] The selected 3D image data, obtained from the extraction, are supplied to the registration module 12 in which the selected 3D image data are correlated with the 3D mapping data provided in step 3 in the correct position and dimension. The 3D mapping data are obtained via a mapping catheter which supplies 3D coordinates of surface points of the heart chamber to be treated via a 6D position sensor integrated into the tip of the catheter. Such catheters are known from the prior art for catheter ablation or, respectively, electroanatomical mapping.

[0031] In this process, the catheter is introduced into the respective heart chamber via veins or arteries by the operator. The guidance of the catheter and the recording of the 3D mapping data is not a component part of an embodiment of the present method. During the catheter ablation or the

electroanatomical measuring of the heart chamber to be treated, respectively, increasingly more surface points are added to the mapping data in the course of time. These surface points are used for reconstructing the morphological

structure of the chamber, i.e. for visualizing it. In this manner, an increasingly more detailed image of the heart chamber to be treated is produced from the electroanatomical 3D mapping data in the course of time.

[0032] In the registration step 4 in the registration module 12, the dimensions of the selected 3D image data and of the 3D mapping data are also matched apart from the correlation in the correct position. This is required in order to achieve the best possible matching of the 3D image data of the heart chamber or of its surface in the same orientation, scaling and shape with the corresponding visualization of the heart chamber from the 3D mapping data. As a rule, this requires a transformation of the selected 3D image data or of the 3D mapping data which can comprise three degrees of freedom of translation, three degrees of freedom of rotation, three degrees of freedom of scaling and/or a number of vectors for the deformation.

[0033] In a first embodiment, the registration can take place by ~~means of~~ visual matching. For this purpose, an operator changes the data visualized until the orientation, scaling and/or shape of the heart chamber displayed matches in both representations, i.e. on the basis of the 3D image data and on the basis of the 3D mapping data. The visual matching can take place via a suitable graphical user interface 9.

[0036] Furthermore, artificial markers can be used for the registration. In one embodiment, the artificial markers can thus be attached to the chest of the patient before recording the 3D image data. These markers remain fixed at the same position during the entire subsequent catheter application. At least three of these markers are required for achieving correct registration, i.e. correlation of the image data with the mapping data. During this process, markers must be used which are both recognizable in the 3D image data_

[0034] and identifiable by the position sensor of the mapping system.

[0035] A further embodiment for registration provides the use of global anatomic markers, i.e. distinct natural points of the area to be treated or its environment, for a registration. These distinct points must be identifiable in the 3D image data and are preferably approached with the mapping catheter by using a fluoroscopic imaging technique. Such distinct points are, for example, the openings of the vena cava superior and inferior or of the coronary sinus. The distinct points can then be detected automatically in the 3D image data and the 3D mapping data so that a correlation of these data with the correct position and dimension can be calculated.

[0036] A further advantageous possibility for the registration of the 3D image data and of the 3D mapping data ~~consists~~ resides in the automatic matching of the surfaces represented on the basis of these data. When the heart chamber to be treated is extracted by ~~means~~ way of segmentation, the extracted 3D surface contour of the heart chamber can be automatically matched to the surface contour of the heart chamber obtained by the 3D mapping data. In the case of deviations in the shape of the surface contours obtained from the 3D image data and the 3D mapping data, deforming matching algorithms can be applied to the surface contour from the 3D image data or to the surface contour from the 3D mapping data in order to improve the mutual mapping.

~~**[0040]**~~ The surface matching can be performed, for example, by reducing or even minimizing point spaces between surface points of the mapping data and surface points of the 3D surface contour extracted from the 3D image data (point-to-point matching). As an alternative, the matching can also be performed by reducing or even minimizing point spaces between

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surface points of the mapping data and interpolated matching
points of the 3D_

[0037] image data (point-to-surface matching).

[0038] The surface matching requires a good surface representation by the 3D mapping data of the heart chamber to be treated. However, since these data are collected over a relatively long period of time, as a rule, i.e. only few electroanatomical 3D mapping data are available at the beginning of the catheter ablation, a multi-stage process of the registration is preferably performed. In this process, a registration by a marker takes place in an initial first stage. The accuracy of the registration is then improved in the course of the process by surface matching in a second step.

[0039] Naturally, further steps of surface matching, by ~~means~~ of which a further increase in accuracy is possibly provided, can also be performed with the increasing number of mapping points. This multi-stage registration is of advantage since registration by surface matching, with a correspondingly good surface representation, is more accurate than registration by ~~means-way~~ of anatomical distinct points or artificial markers, but a good surface representation is only obtained in a later course of an embodiment of the method by the mapping data.

[0040] In the initial first stage, a combination of a registration by ~~means-way~~ of markers and of a registration by ~~means-way~~ of surface matching can also be effected. Thus, for example, a registration of the left atrium by surface matching of a vessel surface, e.g. of the pulmonary artery, and additionally by ~~means-way~~ of distinct anatomical points of the right atrium, e.g. of the coronary sinus or of the opening of the vena cava inferior or of the vena cava superior, can be effected.

~~[0044]~~ After the registration between the 3D mapping data and the selected 3D image data, the data are provided in the

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visualization module 13 in step 5 for the purpose of
visualization such_

[0041] that they can be shown in the correct position and dimension next to one another using one or more display units 6. The dashed arrow in the figure indicates the possibility of refining the registration or superimposition during the catheter ablation by means of a multi-stage process as has already been explained above.

[0042] For the visualization, different techniques can be used. In one refinement, the selected 3D image data can thus be visualized by ~~means~~ way of a volume rendering technique, with the visualization being able to be influenced by adjusting the volume rendering transfer function 7. Since the visualization of the 3D mapping data contains the visualization of the position and orientation of the mapping catheter, it is also possible to superimpose the representation of the position and orientation of the mapping catheter on the selected 3D image data.

[0043] In a further embodiment, in the case of segmentation of the 3D image data, the surface extracted from the 3D image data can also be visualized as surface-shaded representation or, after triangulation, as polygonal grid. In this case, too, it is possible to display the position and orientation of the mapping catheter together with the polygonal grid representing the surface.

[0044] In one advantageous embodiment of the method, and of the associated device, the two visualizations are linked to one another such that they can be moved, rotated and scaled simultaneously. In addition, a "linked cursor" can be used which shows respective corresponding positions in the visualization of the 3D image data and in the visualization of the 3D mapping data. When the cursor is moved by a user in one of the visualizations, the cursor then moves accordingly in the other visualization.

[0045] In addition, the mapping catheter, whose representation is contained in the 3D mapping data and which can be identified in the visualization of these data, as already indicated, can also be overlaid on the visualization of the selected 3D image data when there is appropriate registration between the 3D image data and the 3D mapping data. In this way, the positioning and orientation of this catheter can also be identified at any time in the visualization of the selected 3D image data.

[0046] Example embodiments being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the present invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.